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| 09 885,361 | 06 20 2001 | Birendra K. Patnaik | 498-128 CPA CON | 4945 |

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EXAMINER

MICHENER, JENNIFER KOLB

ART UNIT PAPER NUMBER

1762

DATE MAILED: 06 04 2003

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/885,361

Applicant(s)

PATNAIK ET AL

Examiner

Jennifer Kolb Michener

Art Unit

1762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 21 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 27-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 27-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 6) ☐ Other.

DETAILED ACTION

Election/Restrictions

1. Examiner notes with appreciation Applicant's cancellation of non-elected claims
2. Applicant's election with traverse of Group V. claims 27-30, in Paper No. 12 is acknowledged. The traversal is on the ground(s) that there is no serious burden in searching all of the distinct inventions. This is not found persuasive because the searches for the distinct method steps and chemical compositions of the independent inventions are different. The prior art directed to one independent invention would be different than that directed to another. Additionally, different issues will arise during prosecution of the various inventions.

The requirement is still deemed proper and is therefore made FINAL.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The elected claims as written are not directed to EPTFE caliber vascular grafts with significant patency enhancement via a surface coating which contains covalently bonded heparin.

The following title is suggested: Method of imparting a bio-active coating.

Examiner Suggestion

4. In claim 27, R' is defined as O=C-NH. Since R¹, not R', is what is present in the chemical formula, Examiner suggests that R' may be a typographical error and be changed to R¹.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In claim 27 b), the first "NH" group of the chemical formula beginning "P-R¹-NH- R²..." appears to be new matter.

Throughout the instant specification, this particular "NH" group is not present between the R¹ and R² groups (see pages 8, 9, 12, 13, and 19). Because R¹ is defined as "O=C-NH", Examiner suggests that perhaps the "NH" may have been put into the claim as an inadvertent redundancy.

Art Unit: 1762

7. Claims 27-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

In claim 27 b), the first "NH" group of the chemical formula beginning "P-R¹-NH- R²..." is not described in the specification in such a way as to enable one skilled in the art to make or use this invention.

Throughout the specification the chemical formula beginning "P-R¹-R²..." is used to describe Applicant's coating composition. Applicant defines R¹ to be either "O=C-NH" or "NH", an amide or amine group, respectively. On page 19, Applicant outlines the mechanism by which the composition is made when R¹ is "O=C-NH", an organic amide group, and on pages 20-21, Applicant outlines the mechanism by which the composition is made when R¹ is to be "NH", an amine group. The use of the amide or amine group is used in the alternative throughout the specification to provide direct linkages between the polymer and the spacer. Therefore, the specification does not enable one of ordinary skill in the art to make or use a chemical composition containing both the amine and amide group as linkages between the spacer and polymer.

Art Unit: 1762

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 is unclear. Claim 29 requires the bio-active agent to be one of oxygenated polyolefins, aliphatic polyesters, polyamino acids, etc. The chemicals listed do not appear to be bio-active in nature. Furthermore, these chemicals are used to describe the spacer chemical, not the bio-active agent, in the specification. It is not clear to what chemical claim 29 is referring.

Prior Art of Record

9. Examiner notes that the first "NH" group (as discussed above in the new matter rejection) may have been inadvertently included in the formula of claim 27 as a typographical error. In the event that this is a typographical error, in order to advance and expedite prosecution, Examiner cites Narayanan (US 5,244,654) as potential prior art that Examiner would apply if the "NH" group is removed from the claim to correct the 112 1st rejections. This art would essentially meet the limitations of the claims:

10. Narayanan teaches a method of imparting a coating to a surface of a medical article. The coating of Narayanan contains heparin, a drug, which qualifies as "bio-

Art Unit: 1762

active", as required by Applicant's claim (abstract; examples: col. 3, line 59; col. 6, line 12).

Narayanan teaches plasma treating the surface and a gaseous material of air and water vapor in a plasma chamber to generate carboxyl groups on the surface (col. 4, lines 2, 15, 35-39, and 48-49). Plasma chambers are ionization chambers.

Narayanan teaches the formation of a bio-active composition containing a polymer, a hydrophilic amine-terminated spacer, and a bio-active agent (col. 3, line 35, col. 3, line 39; col. 5, lines 32-55; col. 6, lines 3-7). The polymer is inherently bio-compatible as it is used in the human body. The polyethyleneimine spacer is hydrophilic. At the time of completion of this formation, the composition will be "contacting the surface" as required in claim 27 b).

Regarding the chemical formula of claim 27 b), Examiner notes that this bio-active composition requires a bio-compatible polymer, a hydrophilic amine-terminated spacer, and a bio-active agent (all of which are taught by Narayanan above), with an "O=C-NH" group linking the polymer to the spacer and another "O=C-NH" group linking the spacer to the bioactive agent.

It is Examiner's position that the "O=C-NH" groups required by Applicant are inherently formed in the process of Narayanan. As evidence of such inherency, Examiner points Applicant to page 19 of the instant specification, which outlines the method by which the formula of claim 27 is formed. Applicant teaches that polyurethane with carboxyl

Art Unit: 1762

functionality undergoes a dehydration (otherwise known as condensation) reaction with an amine terminated polyethylene spacer (II) using the carbodiimide agent on page 25 (the agent is abbreviated as EDC). The use of EDC creates the $O=C-NH$ group between the carboxyl functionality of the polyurethane and the amine functionality of the spacer (III). This product then undergoes another dehydration (or condensation) reaction with a bio-active agent in which another $O=C-NH$ group is formed between the amine functionality of the spacer and the carboxyl groups of the bioactive agent (IV). Likewise, Narayanan teaches that polyurethane (col. 3, line 35) with carboxyl groups thereon (col. 4, line 38) undergoes a condensation reaction with an ethylene-based amine-terminated spacer (col. 5, line 45) using the same carbodiimide (EDC) coupling agent (col. 5, line s 54-59) as Applicant. Therefore, the same $O=C-NH$ group must inherently be formed between Narayanan's carboxyl functionality of the polyurethane and the amine functionality of the spacer as Applicant. This product then undergoes another condensation reaction with a bio-active agent in which another $O-C-NH$ group is inherently formed between the secondary amine functionality of the spacer and the carboxyl groups of the bioactive agent (col. 6, lines 3-9).

For these reasons, the formula of claim 27 would be met by Narayanan.

Regarding claim 28, the bio-compatible polyurethane polymer of Narayanan contains carboxyl functionality, as outlined above.

Art Unit: 1762

Regarding claims 29-30, Narayanan teaches the use of heparin as the bio-active agent. Heparin is a linear polysaccharide, by definition, and functions as an anti-thrombogenic agent (col. 6, line 12).

11. Additional prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hu et al. '372 teaches coating a medical article with heparin via amine-terminated spacers attached to polyurethane coated substrates. Hu fails to teach plasma treatment. Hu et al. '556 teaches a chemical formula similar to that required by Applicant (Figure 2, APU), but the plasma treatment used by Hu is used to create a *hydrophobic* environment on the medical article, instead of a hydrophilic environment.

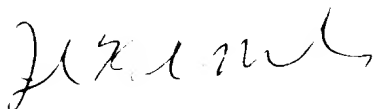
Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kolb Michener whose telephone number is 703-306-5462. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 703-308-2333. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9311 for After Final communications.

Art Unit: 1762

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

A handwritten signature in cursive script, appearing to read "J. Kolb Michener".

Jennifer Kolb Michener
Patent Examiner
Technology Center 1700
June 2, 2003